King, Valerie A.

From: Zedler, Barbara

Sent: Friday, February 13, 2004 11:09 AM

To: Adams, Candace R.; Feng, Shixia; Gogova, Maria; Jin, Yan; King, Valerie A.; Kinser, Robin D.; Liang, Qiwei; Mawyer, Denise T.; Mendes, Paul; Nelson, Bettie L; Oey, Jan; Roethig, Hans; Sarkar, Mohamadi; Unverdorben, Martin; Wang, Jingzhu; Hayden, Angela D.; Kapur, Sunil V.

Cc: Zedler, Barbara

Subject: 24h urine collection CE Clin Process

Sensitivity: Confidential

DSS:

All,

Here is the final document based on the discussion at staff mtg Wed. Mohamadi is working on a flow diagram, particularly for the clin site role in this, to make the process as crystal clear and easy to follow as possible. Pls review carefully and incorporate elements into your area of work as necessary (e.g., study mgrs, data mgmt/ana). To further improve the reliability and accuracy of our urine biomarker results, we will investigate the use of an alternative creatinine assay method (e.g., creatininase instead of Jaffe) and the use of untimed ("spot") or shorter timed (e.g., 2-h) urine collections instead of 24-h collections. However, the attached is now our current standard and will be sent for implementation to the clinical site with a flow diagram. Pls let me know if any questions, additonal comments.

Barb

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